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| Applicant  | : | Lars Tommy Westbye, et al. |
| Appl. No.  | : | 10/626,218                 |
| Examiner   | : | Catherine Witzcak          |
| Docket No. | : | 706737.4003                |

### **Remarks/Arguments**

Reconsideration of this application is requested. Claims 2 and 34 have been amended to more completely and accurately define the subject matter being claimed.

#### **I. Allowable Subject Matter**

Applicant notes with appreciation the Examiner's finding that claims 2-4 contain allowable subject matter. Claim 2 has been rewritten in independent form as suggested by the Examiner. Claims 3 and 4 depend from claim 2 and therefore incorporate all of the limitations of this base claim.

#### **II. Section 103 Rejection**

Claims 1, 5-15 and 17-48 stand rejected under 35 USC §103, as being anticipated by Bitdinger et al (USP 5,478,316) as modified by Bitdinger. Applicant respectfully traverses this rejection because Bitdinger fails to show all of the elements of the claimed invention.

The purported shield – which is described in Bitdinger as sleeve 28 – of the Bitdinger reference does not function in the manner specified in Applicant's claimed invention. Furthermore, there is no teaching or motivation within Bitdinger to modify the sleeve 28 to function in the manner claimed by Applicant.

As shown in Figures 3-5 and 9 of Bitdinger and described in col. 3, lines 51-60, the sleeve 28 is biased to an extended position. In fact, in the resting, pre-administration position, the sleeve 28 of the Bitdinger device extends over the needle. "The spring 40 causes the sleeve to extend over the needle in its rest position, as shown in FIGS. 3 and 9." Bitdinger, col. 3, lines 59-60. The only time the sleeve 28 retracts is during administration when the "end of the sleeve 28 is pressed against the epidermis." Bitdinger, col. 5, line 50.

In contrast, the shield of the present application is retracted in the resting position and in this configuration does not cover the needle. It is only during administration that the release mechanism is actuated so that the shield extends to the extended position to cover the needle.

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| Examiner   | : | Catherine Witczak          |
| Docket No. | : | 706737.4003                |

Therefore, Bitdinger fails to describe or teach a system comprising a shield that is in a retracted position prior to administration.

### III. Section 103 Rejections

Claim 16 is rejected under 35 USC § 103 as being unpatentable over Bitdinger in view of Holman (USP 5,104,380). As demonstrated above, Bitdinger fails to disclose, teach or suggest each and every element of independent claim 1 from which claims 16 depends, and therefore, it is respectfully submitted that claim 16 is not obvious in light of the combination of Bitdinger and Holman.

### IV. Conclusion

In view of the foregoing, favorable reconsideration of this application and a Notice of Allowance is earnestly solicited. Should the Examiner have any questions or comments, the undersigned can be reached at (949) 567-6700. The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 150665.

Respectfully submitted,

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